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May 15, 2024

Honorable Judge James Donato San Francisco Courthouse, Courtroom 11, 19th Floor 450 Golden Gate Avenue, San Francisco, CA 94102

Re: Nektar Therapeutics v. Eli Lilly and Company, 23-cv-3943-JD (N.D. Cal.)

Dear Judge Donato,

I write on behalf of Plaintiff Nektar Therapeutics regarding certain discovery disputes with Defendant Eli Lilly and Company. Briefly, Lilly has objected to Nektar's requests for production ("RFPs") and, despite multiple meet-and-confers, will not agree to Nektar's proposed compromises on the RFPs' scope. Without the Court's intervention, Nektar will be unable to obtain important discovery for its claims. Lilly also refuses to include certain custodians despite Nektar's explanation that these individuals likely possess highly relevant, non-duplicative discovery. Nektar certifies that the parties have conferred in person regarding the disputed issues in accordance with the Court's Standing Order and the Local Rules.

# I. <u>Lilly Refuses to Provide Discovery that Permits a Proper Comparison Between</u> Rezpeg Development and Development of "Comparable" Drugs

Nektar's Complaint alleges Lilly breached the parties' joint development agreement concerning Nektar's drug Rezpeg ("Agreement"). Executed in 2017, the Agreement obligated Lilly to undertake "Commercially Reasonable Efforts" ("CRE") in Rezpeg development, which required Lilly to use the "effort, expertise and resources" that Lilly "normally used" to develop and commercialize "comparable" products "at a similar stage of development." Dkt. 61 (FAC) ¶¶ 18-19; Dkt. 33-2 (Agreement) §§ 1.1, 4.5. Whether Lilly used CRE in Rezpeg development (or not) is measured against the "effort, expertise and resources *normally* used by [Lilly] in the development . . . of a *comparable* pharmaceutical product" according to various factors: "safety and efficacy, product profile, the competitiveness of the marketplace, the proprietary position of the compound or product, the regulatory structure involved, the profitability of the applicable products, product reimbursement and other relevant strategic and commercial factors normally considered by [Lilly] in making product portfolio decisions." Dkt. 33-2, § 1.1 (emphasis added).

Nektar alleges that Lilly failed to use CRE to develop Rezpeg and that Lilly breached the Agreement's implied covenant by sabotaging Rezpeg to avoid milestone and royalty payments and to benefit Lilly's competing drug, lebrikizumab. Dkt. 61 ¶ 86, 94, 100, 104, 109-112. The disputed RFPs seek discovery to enable Nektar to prove its claims, as each RFP concerns Lilly's "normal" activities to develop "comparable" drugs and/or Lilly's acquisition and development of lebrikizumab. These inquiries are necessarily fact-intensive, as is the nature of CRE disputes.

<sup>&</sup>lt;sup>1</sup> To date—more than 10 months after this case was filed—Lilly has produced fewer than 3,000 documents, making its first production only two days ago.

E.g., Docklight Brands Inc. v. Tilray Inc., 2023 WL 5206392, at \*2 (W.D. Wash. Aug. 14, 2023) (granting discovery requests on party and third party worldwide "sales, marketing, expenses, and financials" as "broadly relevant to establishing a baseline . . . to which Defendants' results might be compared" and relevant to "what constitutes commercially reasonable efforts"). As the parties did not reach settlement in mediation, Nektar needs this discovery to prepare for trial.

#### A. Nektar Is Entitled to Discovery on Pre-2017 Drug Development

For certain RFPs, Lilly has taken the position that it will only produce discovery for drugs developed between 2017 and 2023—the period that the Agreement was effective. *See* Ex. A (RFP Nos. 23, 39-48, 53-54). Lilly's objection is improper for several reasons. In artificially restricting CRE to refer to contemporaneous drug development, Lilly effectively rewrites the Agreement. The actual CRE definition is not limited in this way. Indeed, it would make no sense to measure what Lilly "normally" does by looking only to its activities after the execution of the Agreement; the CRE definition necessarily requires looking at Lilly's past conduct to evaluate its compliance.

The requested discovery is highly relevant. To prove breach of CRE, Nektar seeks to establish Lilly's "normal" practices, which include Lilly's development of drugs for case-relevant diseases (eczema, psoriasis, and lupus) both before and after execution of the Agreement. To this end, its requests are targeted to specific, critical metrics of comparison—*e.g.*, budgeting (RFP No. 23), oversight and engagement of contractors (39, 41) and clinical trial conduct (40, 42-48). These comparisons are *fundamental* both to Nektar's breach claims, and to Lilly's defenses.

Nektar's requests are also proportional. In correspondence and conferrals, Nektar has reiterated that it seeks documents that will enable Nektar to make a comparison between Lilly's development of Rezpeg and its development of comparable drugs. Nektar does not need, nor want, every scrap of paper generated in the development of those other drugs. But Lilly should not be permitted to exclude relevant discovery arbitrarily based on when the drugs were developed.

#### B. Nektar Is Entitled to Discovery that Does Not Explicitly Mention Rezpeg

Lilly also objects to providing certain discovery concerning other drugs if that discovery does not also refer to Rezpeg. See Ex. A (RFP Nos. 12-17, 19-21, 23, 26, 31, 49, 50-57, objecting on relevance grounds "to the extent unrelated to REZPEG" or otherwise where documents are not directly linked to Rezpeg development efforts). As further confirmed in correspondence and conferrals, Lilly's position is based on a deeply flawed premise—that a document is only relevant and responsive if the author was writing about both Rezpeg and the comparator drug in the same document. Not so. Documents concerning other drugs may show the efforts Lilly "normally" exerts, the expertise it "normally" uses, and the resources it "normally" expends in the development of such drugs, and therefore are directly relevant to the issue of Lilly's breach of its obligation to exercise CRE in the development of Rezpeg. Indeed, Lilly's responses to Nektar's interrogatories acknowledge the need to examine Lilly's conduct in developing comparable pharmaceutical products, regardless of whether that conduct affected Rezpeg. The RFPs at issue target essential comparisons—e.g., efficacy (RFP Nos. 12, 50), safety (13-14, 49, 51), consumer sentiment (17, 52), strategic financial decisions (19, 23, 26, 31, 53, 54), and clinical conduct (55-57). While, again, Nektar does not need every scrap of paper, Lilly should not be permitted a wholesale exclusion of relevant discovery.

# C. Nektar Is Entitled to Discovery on Comparable Drugs at a Similar Stage of Development

Lilly also objects to providing certain discovery concerning other drugs if their studies were not exactly the same indication and phase as a corresponding Rezpeg trial. *See* Ex. A (same RFPs as I.B). But CRE requires a comparison to "comparable" drugs "at a similar stage of development," not an "identical" stage. Nektar should not be limited to discovery only on the *same* trial phase(s), and for the *same* disease(s), as in Rezpeg development. Lilly's objection has no basis.

#### II. Lilly Refuses to Add Custodians with Relevant, Non-Duplicative Information

Each party has requested that the other collect documents from the same number of custodians (17).<sup>2</sup> Lilly has rejected three of Nektar's requested custodians on the basis of burden, duplication, and relevance: Lilly CEO David Ricks, President of Immunology Patrik Jonsson, and SVP of Global Immunology Development Lotus Mallbris. However, "[c]ourts regularly add high-ranking executives as custodians where their files are likely to contain relevant information." *In re Facebook, Inc. Consumer Priv. User Profile Litig.*, 2021 WL 10282213, at \*5 (N.D. Cal. Nov. 14, 2021) (compelling addition of Facebook "key decision-makers"); *Shenwick v. Twitter, Inc.*, 2018 WL 833085, at \*1 (N.D. Cal. Feb. 7, 2018) (compelling addition of Twitter CEO).

Here, Mr. Ricks signed the Agreement for Lilly and had final decision-making power concerning Rezpeg development. He will almost certainly have relevant documents that Lilly's technical development team is unlikely to possess—*e.g.*, communications with other C-suite individuals concerning product prioritization in Lilly's overall portfolio and allocation of resources. Lilly admitted it has not taken any effort to ascertain the scope of any actual burden and its claims are therefore purely speculative. Public materials and Lilly's production to-date indicate Drs. Jonsson and Mallbris were heavily involved in Lilly's development and acquisition of competing products, particularly lebrikizumab. Their non-duplicative documents will show the "effort, expertise and resources normally used by" Lilly for development of comparable drugs, and enable a comparison to Lilly's actions in developing Rezpeg—as required by the definition of CRE in the Agreement.

Additionally, if these individuals have few or overlapping responsive documents, Lilly can alleviate any incremental burden by de-duplicating this discovery prior to review and production.

Lilly should not be permitted to use discovery as both a shield and sword—first by blocking access to relevant discovery, then turning around to argue that Nektar has failed to prove its claims. Nektar respectfully requests that the Court order Lilly to produce the documents noted above and include the additional custodians in its document collection and production.

Very truly yours,
/s/ Yury Kapgan
Yury Kapgan
Attorney for Plaintiff Nektar Therapeutics

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<sup>&</sup>lt;sup>2</sup> Nektar agrees to provide this discovery as a good-faith compromise. This case centers on *Lilly's* alleged breaches, however, and the relevance of 17 *Nektar* custodians—many with similar roles—is not apparent.

# **EXHIBIT A**

#### **DEFINITIONS**

The following definitions and instructions apply to each Request for Production:

- 1. "Lilly," "Defendant," or "You[r]" means Eli Lilly & Co. and includes each of its officers, directors, members, managers, agents, consultants, contractors, employees, attorneys, accountants, partners, corporate parents, subsidiaries, affiliates, divisions, predecessors-in-interest, successors-in-interest, and any person or entity, past or present, who acts on Eli Lilly & Co.'s behalf or purports to act on Eli Lilly & Co.'s behalf.
  - 2. "Nektar" or "Plaintiff" means Nektar Therapeutics.
- 3. "Lawsuit" means the above-captioned action, *Nektar Therapeutics v. Eli Lilly & Co.*, Case No. 3:23-cv-03943 (N.D. Cal.).
- 4. "REZPEG" means rezpegaldesleukin. REZPEG shall be construed to include NKTR-358 and LY3471851.
- 5. "Agreement" means the License Agreement dated July 23, 2017 between Nektar and Lilly with respect to, *inter alia*, the development of REZPEG.
  - 6. "Compound" shall have the meaning set forth in Section 1.1 of the Agreement.
- 7. "Eczema Study" means the Phase 1 clinical trial of REZPEG in patients with atopic dermatitis, titled "A Phase 1, Double-Blind, Randomized, Placebo-Controlled, Multiple-Dose Study to Evaluate the Safety, Tolerability, and Pharmacokinetics of Subcutaneous LY3471851 in Patients With Atopic Dermatitis" (Clinical Trial ID No. NCT04081350), also known as J1P-MC-KFAD. For the avoidance of doubt, and without limitation, the Eczema Study shall be construed to extend to plans, understanding, and efforts concerning such study before it was designed or performed, the conduct of such study whether by You, Nektar, or a third party, and any analysis or understanding of such study after its conclusion.

8. "Eczema Phase 2 Study Design" means any and all proposals, designs, plans, preparations, analyses, presentations, memoranda, and Communications with respect to Your development of a Phase 2 clinical study of REZPEG in patients with atopic dermatitis.

- 9. "Psoriasis Study" means the Phase 1 clinical trial of REZPEG in patients with psoriasis, titled "A Phase 1, Double-Blind, Randomized, Placebo-Controlled, Multiple-Dose Study to Evaluate the Safety, Tolerability, and Pharmacokinetics of Subcutaneous LY3471851 in Patients With Psoriasis" (Clinical Trial ID No. NCT04119557), also known as J1P-MC-KFAC. For the avoidance of doubt, and without limitation, the Psoriasis Study shall be construed to extend to plans, understanding, and efforts concerning such study before it was designed or performed, the conduct of such study whether by You, Nektar, or a third party, and any analysis or understanding of such study after its conclusion.
- 10. "Lupus Study" means the Phase 2 clinical trial of REZPEG in patients with systematic lupus erythematosus, titled "A Randomized, Double-Blind, Placebo-Controlled, Phase 2 Study of LY3471851 (NKTR-358) in Adults With Systemic Lupus Erythematosus" (Clinical Trial ID No. NCT04433585), also known as J1P-MC-KFAJ. For the avoidance of doubt, and without limitation, the Lupus Study shall be construed to extend to plans, understanding, and efforts concerning such study before it was designed or performed, the conduct of such study whether by You, Nektar, or a third party, and any analysis or understanding of such study after its conclusion.
- 11. "Autoimmune Disease" means a disease or disorder caused by autoimmune pathology, including but not limited to psoriasis, atopic dermatitis (eczema), and systematic lupus erythematosus.
- 12. "Document" has the full meaning ascribed to it by the Federal Rules of Civil Procedure and shall include any means for retaining or reflecting information.
  - 13. "Thing" means any tangible item other than a Document.
- 14. "Communication" means any correspondence, communication, and/or conveyance of information in any form, including orally, visually, electronically, in writing, graphically, or in a Document.

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15. The term "Concerning" means relating to, referring to, bearing on, regarding, describing, evidencing, reflecting, comprising, or constituting.

- 16. The terms "include" and "including" shall be deemed to be followed by the words "without limitation."
- 17. "Person" means any natural person or any business, legal, or governmental entity or
- 18. "And" and "or" shall be construed conjunctively or disjunctively as necessary to make the request inclusive rather than exclusive; use of a singular noun shall be construed to include the plural noun and use of a plural noun shall be construed to include the singular noun; and the use of a verb in any tense shall be construed as the use of that verb in all other tenses whenever necessary to bring within the scope of the request that which might otherwise be construed to be outside its scope.
- 19. The term "all" and "any" means, each, every, all, and/or "any and all," and should be interpreted broadly to bring within the scope of these requests Documents and Things that might otherwise be construed to be outside their scope.

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#### **REQUEST FOR PRODUCTION NO. 12:**

All Documents, Communications, and Things Concerning the actual or potential efficacy of REZPEG, Dupixent® (dupilumab), and lebrikizumab.

#### **RESPONSE TO REQUEST FOR PRODUCTION NO. 12:**

Lilly objects to this Request as vague, ambiguous, overly broad, unduly burdensome, and not proportional to the needs of the case, including because it seeks "[a]ll Documents, Communications, and Things Concerning the actual or potential efficacy of REZPEG, Dupixent® (dupilumab), and lebrikizumab" and is unlimited in timeframe. Lilly further objects to this Request as not relevant to the claims or defenses of a party to the extent it requests documents beyond the scope of this dispute.

Subject to and without waiving its General and Specific Objections, Lilly will conduct a reasonable search for and produce responsive, non-privileged documents relating to the actual or potential efficacy of REZPEG as it relates to Lilly's efforts, development decisions, and strategy regarding REZPEG, including documents reflecting Lilly's consideration of such efficacy in relation to Dupixent and lebrikizumab. Lilly will not search for or produce documents solely related to the efficacy of Dupixent or lebrikizumab to the extent unrelated to REZPEG, the allegations in the Complaint, or the issues in dispute in this action.

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#### **REQUEST FOR PRODUCTION NO. 13:**

All Documents, Communications, and Things Concerning the actual or potential safety of REZPEG, Dupixent® (dupilumab), and lebrikizumab.

#### **RESPONSE TO REQUEST FOR PRODUCTION NO. 13:**

Lilly objects to this Request as vague, ambiguous, overly broad, unduly burdensome, and not proportional to the needs of the case, including because it seeks "[a]ll Documents, Communications, and Things Concerning the actual or potential safety of REZPEG, Dupixent® (dupilumab), and lebrikizumab" and is unlimited in timeframe. Lilly further objects to this Request as not relevant to the claims or defenses of a party to the extent it requests documents beyond the scope of this dispute.

Subject to and without waiving its General and Specific Objections, Lilly will conduct a reasonable search for and produce responsive, non-privileged documents relating to the actual or potential safety of REZPEG as it relates to Lilly's efforts, development decisions, and strategy regarding REZPEG, including documents reflecting Lilly's consideration of such safety in relation to Dupixent and lebrikizumab. Lilly will not search for or produce documents solely related to the safety of Dupixent or lebrikizumab to the extent unrelated to REZPEG, the allegations in the Complaint, or the issues in dispute in this action. **REQUEST FOR PRODUCTION NO. 14:** 

All Documents, Communications, and Things Concerning comparisons of the prevalence and severity of injection site reactions associated with injectable drug therapies for Autoimmune Diseases, including but not limited to REZPEG, Dupixent® (dupilumab), and lebrikizumab, and methods of evaluating such reactions.

#### **RESPONSE TO REQUEST FOR PRODUCTION NO. 14:**

Lilly objects to this Request as vague, ambiguous, overly broad, unduly burdensome, and not proportional to the needs of the case, including because it seeks "[a]ll Documents, Communications, and Things Concerning comparisons of the prevalence and severity of injection site reactions associated with

injectable drug therapies for Autoimmune Diseases" and is unlimited in timeframe. Lilly further objects to this Request as not relevant to the claims or defenses of a party to the extent it requests documents beyond the scope of this dispute.

Subject to and without waiving its General and Specific Objections, Lilly will conduct a reasonable search for and produce responsive, non-privileged documents relating to comparisons of the prevalence and severity of injection site reactions associated with REZPEG to other injectable therapies including Dupixent and lebrikizumab, and the methods of evaluating such reactions.

#### **REQUEST FOR PRODUCTION NO. 15:**

All Documents, Communications, and Things Concerning the decision-making criteria utilized by physicians and/or patients when choosing between injectable drug therapies for Autoimmune Diseases.

#### **RESPONSE TO REQUEST FOR PRODUCTION NO. 15:**

Lilly objects to this Request as vague, ambiguous, overly broad, unduly burdensome, and not proportional to the needs of the case, including because it seeks "[a]ll Documents, Communications, and Things Concerning the decision-making criteria utilized by physicians and/or patients when choosing between injectable drug therapies for Autoimmune Diseases" and is unlimited in timeframe. Lilly further objects to this Request as not relevant to the claims or defenses of a party to the extent it requests documents beyond the scope of this dispute.

Subject to and without waiving its General and Specific Objections, Lilly will conduct a reasonable search for and produce responsive, non-privileged documents relating to Lilly's consideration of decision-making criteria utilized by physicians and/or patients when choosing between injectable drug therapies for autoimmune diseases in the context of Lilly's development decisions, efforts, and strategy regarding REZPEG.

#### **REQUEST FOR PRODUCTION NO. 16:**

All Documents, Communications, and Things Concerning Your understanding of injection site reactions associated with injectable drug therapies for Autoimmune Diseases, including but not limited to REZPEG, Dupixent® (dupilumab), and lebrikizumab.

#### **RESPONSE TO REQUEST FOR PRODUCTION NO. 16:**

Lilly objects to this Request as vague, ambiguous, overly broad, unduly burdensome, and not proportional to the needs of the case, including because it seeks "[a]ll Documents, Communications, and Things Concerning Your understanding of injection site reactions associated with injectable drug therapies for Autoimmune Diseases" and is unlimited in timeframe. Lilly further objects to this Request as not relevant to the claims or defenses of a party to the extent it requests documents beyond the scope of this dispute.

Subject to and without waiving its General and Specific Objections, Lilly will conduct a reasonable search for and produce responsive, non-privileged documents relating to Lilly's understanding of injection site reactions associated with REZPEG.

#### **REQUEST FOR PRODUCTION NO. 17:**

All Documents, Communications, and Things Concerning the commercial acceptability of injection site reactions associated with injectable drug therapies for Autoimmune Diseases, including any analysis, interviews, studies, investigations, research, surveys, questionnaires, or drafts thereof designed by You with respect to REZPEG and/or lebrikizumab, and any analysis of the results of such analysis, interviews, studies, investigations, research, surveys, and/or questionnaires.

#### **RESPONSE TO REQUEST FOR PRODUCTION NO. 17:**

Lilly objects to this Request as overly broad, unduly burdensome, and not proportional to the needs of the case, including because it seeks "[a]ll Documents, Communications, and Things Concerning the commercial acceptability of injection site reactions associated with injectable drug therapies for Autoimmune Diseases," "any analysis interviews, studies, investigations, research, surveys, questionnaires, or drafts," and is unlimited in timeframe. Lilly also objects to this request as vague and ambiguous, including because "commercial acceptability" is undefined. Lilly further objects to this Request as not relevant to the claims or defenses of a party to the extent it requests documents concerning the commercial impact of injection site reactions associated with injectable drug therapies for autoimmune diseases unrelated to REZPEG.

Subject to and without waiving its General and Specific Objections, Lilly will conduct a reasonable search for and produce responsive, non-privileged documents relating to Lilly's assessment of the impact

of injection site reactions associated with REZPEG on the potential commercialization of REZPEG, including to the extent such assessment included information or analysis about the commercial impact of injection site reactions associated with other injectable drugs for autoimmune diseases.

#### **REQUEST FOR PRODUCTION NO. 19:**

All Documents, Communications, and Things Concerning Your acquisition of Dermira, Inc.

#### **RESPONSE TO REQUEST FOR PRODUCTION NO. 19:**

Lilly objects to this Request as vague, ambiguous, overly broad, unduly burdensome, and not proportional to the needs of the case, including because it seeks "[a]ll Documents, Communications, and Things Concerning Your acquisition of Dermira, Inc." and is unlimited in timeframe. Lilly also objects to this Request as not relevant to the claims or defenses of a party to the extent it requests documents beyond the scope of this dispute.

Lilly is willing to meet and confer to narrow the scope of this Request to materials, if any, that are relevant to the allegations in the Complaint and issues in dispute in this action.

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#### **REQUEST FOR PRODUCTION NO. 20:**

All Documents, Communications, and Things Concerning Your commercial strategy for lebrikizumab, including any comparisons, analyses, forecasts, or projections Concerning lebrikizumab and other drug candidates for treating Autoimmune Diseases, including without limitation REZPEG. RESPONSE TO REQUEST FOR PRODUCTION NO. 20:

Lilly objects to this Request as vague, ambiguous, overly broad, unduly burdensome, and not proportional to the needs of the case, including because it seeks "[a]ll Documents, Communications, and Things Concerning Your commercial strategy for lebrikizumab" and is unlimited in timeframe. Lilly also objects to this Request as not relevant to the claims or defenses of a party to the extent it requests documents beyond the scope of this dispute.

Lilly is willing to meet and confer to narrow the scope of this Request to materials, if any, that are relevant to the allegations in the Complaint and issues in dispute in this action.

#### **REQUEST FOR PRODUCTION NO. 21:**

All Documents, Communications, and Things Concerning Your commercial strategy for REZPEG, including any comparisons, analyses, forecasts, or projections Concerning REZPEG and other drug candidates for treating Autoimmune Diseases, including without limitation lebrikizumab.

### **RESPONSE TO REQUEST FOR PRODUCTION NO. 21:**

Lilly objects to this Request as vague, ambiguous, overly broad, unduly burdensome, and not proportional to the needs of the case, including because it seeks "[a]ll Documents, Communications, and Things Concerning Your commercial strategy for REZPEG" and "any comparisons, analyses, forecasts, or projections."

Subject to and without waiving its General and Specific Objections, Lilly will conduct a reasonable search for and produce responsive, non-privileged documents relating to Lilly's commercial strategy for REZPEG.

#### **REQUEST FOR PRODUCTION NO. 23:**

All Documents, Communications, and Things Concerning Your budgeting and/or allocation of resources towards the development of REZPEG, including Your budgeting and/or allocation of resources towards the development of other drug candidates to treat Autoimmune Diseases, including but not limited to lebrikizumab.

#### **RESPONSE TO REQUEST FOR PRODUCTION NO. 23:**

Lilly objects to this Request as vague, ambiguous, overly broad, unduly burdensome, and not proportional to the needs of the case, including because it seeks "[a]ll Documents, Communications, and Things Concerning Your budgeting and/or allocation of resources towards the development of REZPEG" and is unlimited in timeframe. Lilly further objects to this Request as not relevant to the claims or defenses of a party to the extent it requests documents beyond the scope of this dispute. Lilly also objects to this Request to extent it suggests that Lilly's budgeting and/or allocation of resources towards the development of other drug candidates to treat autoimmune diseases necessarily concerns Lilly's budgeting and/or allocation of resources towards the development of REZPEG.

Subject to and without waiving its General and Specific Objections, Lilly will conduct a reasonable search for and produce responsive, non-privileged documents relating to Lilly's budgeting and allocation of resources towards the development of REZPEG. Lilly will also search for and produce responsive non-privileged documents sufficient to show annual financial commitments contemporaneously allocated to comparable lupus, psoriasis, or atopic dermatitis treatments controlled by Lilly at a similar stage of development as REZPEG.

### **REQUEST FOR PRODUCTION NO. 26:**

All Documents, Communications, and Things Concerning estimates or projections of lebrikizumab's financial performance, including without limitation lebrikizumab's probability of clinical success and FDA approval, costs of commercialization, and anticipated timing of launch and biosimilar entry.

#### **RESPONSE TO REQUEST FOR PRODUCTION NO. 26:**

Lilly objects to this Request as overly broad, unduly burdensome, and not proportional to the needs of the case, including because it seeks "[a]ll Documents, Communications, and Things Concerning estimates or projections of lebrikizumab's financial performance" and is unlimited in timeframe. Lilly also objects to this Request as vague and ambiguous with respect to its request for documents concerning "lebrikizumab's financial performance" and "lebrikizumab's probability of clinical success and FDA

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#### **REQUEST FOR PRODUCTION NO. 31:**

All Documents, Communications, and Things Concerning Your efforts to develop and commercialize products with "similar market potential" as set forth in the Agreement.

#### **RESPONSE TO REQUEST FOR PRODUCTION NO. 31:**

Lilly objects to this Request as vague, ambiguous, overly broad, unduly burdensome, and not proportional to the needs of the case, including because it seeks "[a]ll Documents, Communications, and Things Concerning Your efforts to develop and commercialize products with "similar market potential" as set forth in the Agreement" and is unlimited in timeframe. Lilly further objects to this Request as not relevant to the claims or defenses of a party to the extent it requests documents beyond the scope of this dispute. Lilly also objects to this Request to the extent it suggests that the relevant benchmark for Lilly's commercially reasonable efforts obligations under the agreement was only products with "similar market potential."

Lilly is willing to meet and confer to narrow the scope of this Request to materials, if any, that are relevant to the allegations in the Complaint and issues in dispute in this action.

#### **DEFINITIONS**

The following definitions and instructions apply to each Request for Production:

- 1. Nektar hereby incorporates by reference the Definitions set forth in Nektar's First Sets of Interrogatories and Requests for Production dated Nov. 8, 2023.
- 2. "Pharmacokinetic Samples" means biological specimens or samples reflecting the pharmacokinetic properties of REZPEG that Lilly collected with respect to any REZPEG clinical trial, including but not limited to blood samples, serum samples, and plasma samples collected at all time points from all study subjects or patients. This term shall be construed to include any such items collected by and/or in the possession, custody, or control of Lilly and/or any third parties Lilly engaged with respect to such clinical trial.
- 3. "Tissue Samples" means tissue, blood (whole blood, peripheral blood mononuclear cells (PBMCs), serum, plasma and/or DNA and/or RNA extracted from blood), and/or biopsy specimens or samples that Lilly collected with respect to any REZPEG clinical trial and/or throughout the course of the REZPEG clinical program. This term shall be construed to include any such items collected by and/or in the possession, custody, or control of Lilly and/or any third parties Lilly engaged with respect to such clinical trial/program.
- 4. "ICON/PRA" means, individually and collectively, Icon plc, Pharmaceutical Research Associates Health Services, and Pharmaceutical Research Associates CIS, LLC.

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- 5. "Lebrikizumab" shall be construed to include at least TNX-650, LY3650150, Ebglyss, and any other code names or identifiers Lilly, Dermira, Genentech, and/or Roche uses or has used in the development of the drug candidate known as Lebrikizumab.<sup>1</sup>
- 6. "Baricitinib" shall be construed to include at least LY3009104, Olumiant, and any other code names or identifiers Lilly uses or has used in the development of the drug candidate known as baricitinib.
- 7. "Ixekizumab" shall be construed to include LY2439821, Taltz, and any other code names or identifiers Lilly uses or has used in the development of the drug candidate known as ixekizumab.
- 8. "Venanprubart" shall be construed to include LY3361237 and any other code names or identifiers Lilly uses or has used in the development of the drug candidate known as venanprubart.
- 9. "Tabalumab" shall be construed to include LY2127399 and any other code names or identifiers Lilly uses or has used in the development of the drug candidate known as tabalumab.
- 10. "Peresolimab" shall be construed to include LY3462817 and any other code names or identifiers Lilly uses or has used in the development of the drug candidate known as peresolimab.
- 11. "CD19 Antibody" means the CD19 antibody currently in development by Lilly for the treatment of autoimmune diseases<sup>2</sup> and shall be construed to include any other code names or identifiers Lilly uses or has used in the development of this drug.
- 12. "GITR Antagonist" means the GITR antagonist currently in development by Lilly for the treatment of autoimmune diseases and shall be construed to include any other code names or identifiers Lilly uses or has used in the development of this drug.

<sup>&</sup>lt;sup>1</sup> It is Nektar's present understanding that Genentech, Inc. ("Genentech") and/or Roche Holding AG ("Roche") acquired lebrikizumab from Tanox, Inc. ("Tanox") and sold lebrikizumab to Dermira, Inc. ("Dermira"). Accordingly, Requests concerning Lebrikizumab shall include information in Your possession, custody, and control originating from Tanox, Genentech, Roche, and Dermira (individually or collectively).

<sup>&</sup>lt;sup>2</sup> Items described herein as "currently in development by Lilly" relate to the drug candidates reflected at the website "Medicines in Development," https://www.lilly.com/discovery/clinical-development-pipeline.

- 13. "DC-853" means the chemical entity currently in development by Lilly for the treatment of autoimmune diseases and shall be construed to include any other code names or identifiers Lilly uses or has used in the development of this drug.
- 14. "Kv1.3 Antagonist" means the chemical entity currently in development by Lilly for the treatment of autoimmune diseases and shall be construed to include any other code names or identifiers Lilly uses or has used in the development of this drug.
- 15. "Early Stage Candidates" means, individually or collectively, Peresolimab, CD19 Antibody, GITR Antagonist, DC-853, and Kv1.3 Antagonist.
- 16. "Other Eczema Drug Candidates" shall be construed to include at least Lebrikizumab, Baricitinib, and any other drugs and drug candidates owned, licensed, developed, or being developed by Lilly for the treatment of atopic dermatitis (eczema), including any drugs and drug candidates to which Lilly has co-development rights, and any other drug or drug candidate (including Early Stage Candidates) that Lilly contends is a "comparable" drug to REZPEG pursuant to the definition of "Commercially Reasonable Efforts" in the Agreement. Discovery in this litigation is just beginning, and Nektar reserves all rights to modify this definition as further information becomes available to Nektar.
- 17. "Other Psoriasis Drug Candidates" shall be construed to include at least Ixekizumab, Venanprubart, and any other drugs and drug candidates owned, licensed, developed, or being developed by Lilly for the treatment of psoriasis, including any drug and drug candidates to which Lilly has co-development rights, and any other drug or drug candidate (including Early Stage Candidates) that Lilly contends is a "comparable" drug to REZPEG pursuant to the definition of "Commercially Reasonable Efforts" in the Agreement. Discovery in this litigation is just beginning, and Nektar reserves all rights to modify this definition as further information becomes available to Nektar.
- 18. "Other Lupus Drug Candidates" shall be construed to include at least Baricitinib, Tabalumab, and Venanprubart, and any other drugs and drug candidates owned, licensed, developed, or being developed by Lilly for the treatment of lupus, including any drug and drug candidates to which Lilly has co-development rights, and any other drug or drug candidate

(including Early Stage Candidates) that Lilly contends is a "comparable" drug to REZPEG pursuant to the definition of "Commercially Reasonable Efforts" in the Agreement. Discovery in this litigation is just beginning, and Nektar reserves all rights to modify this definition as further information becomes available to Nektar. "Clinical Trial" shall be construed to include any Phase I Study, Phase II Study, 19. Phase II/III Study, and Phase III Study as those terms are defined in Section 1.1 of the Agreement, and shall be construed to extend to plans, understanding, and efforts concerning such study before it was designed or performed, the conduct of such study whether by You or a third party, and any analysis or understanding of such study after its conclusion. 

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#### **REQUEST FOR PRODUCTION NO. 39:**

All policies, instructions, or guidance You provide and/or have provided to any third party that You have engaged to perform statistical analysis of any Clinical Trial(s) of any drug or drug candidate to treat any Autoimmune Disease, including any such materials You provided to ICON/PRA during the development of REZPEG.

#### **RESPONSE TO REQUEST FOR PRODUCTION NO. 39:**

Lilly objects to this Request as vague, ambiguous, overly broad, unduly burdensome, and not proportional to the needs of the case, including because it seeks "[a]ll policies, instructions, or guidance" and is unlimited as to timeframe. Lilly also objects to this Request as not relevant to the claims or defenses of a party to the extent it seeks documents not relevant to whether the efforts, resources, and expertise Lilly devoted to REZPEG satisfied Lilly's commercially reasonable efforts obligations under the parties' License Agreement and to the extent it seeks documents concerning clinical trials and autoimmune diseases that are not relevant to the issues in dispute in this case.

Subject to and without waiving its General and Specific Objections, Lilly will conduct a reasonable search for and produce non-privileged documents sufficient to show the written policies, instructions, and/or guidance Lilly provided to third parties that it engaged to perform statistical analysis of any phase 1 study for atopic dermatitis or psoriasis sponsored by Lilly from 2017 through 2023. Lilly also will conduct a reasonable search for and produce the policies, instructions, and/or guidance it provided to ICON/PRA during the development of REZPEG related to the phase 1 studies of REZPEG for atopic dermatitis and psoriasis.

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#### **REQUEST FOR PRODUCTION NO. 40:**

Documents, Communications, and Things sufficient to show Your "normal" or "usual" "practices" with respect to the conduct of any Clinical Trial(s) of any drug or drug candidate to treat any Autoimmune Disease.

#### **RESPONSE TO REQUEST FOR PRODUCTION NO. 40:**

Lilly objects to this Request as overly broad, unduly burdensome, and not proportional to the needs of the case, including because it is unlimited as to timeframe. Lilly also objects to this Request as vague and ambiguous to the extent it seeks documents concerning "the conduct of any Clinical Trial(s)." Lilly further objects to this Request as not relevant to the claims or defenses of a party to the extent it seeks documents not relevant to whether the efforts, resources, and expertise Lilly devoted to REZPEG satisfied Lilly's commercially reasonable efforts obligations under the parties' License Agreement and to the extent it seeks documents concerning clinical trials and autoimmune diseases that are not relevant to the issues in dispute in this case.

Subject to and without waiving its General and Specific Objections, Lilly will conduct a reasonable search for and produce the protocols, statistical analysis plans, specifications, and related agreements and work orders with any third party involved in the statistical analysis for any phase 1 study for atopic dermatitis or psoriasis sponsored by Lilly from 2017 through 2023 and the protocols and statistical analysis plans for any phase 2 atopic dermatitis and systemic lupus erythematosus ("SLE") studies sponsored by Lilly from 2017 through 2023.

#### **REQUEST FOR PRODUCTION NO. 41:**

Documents, Communications, and Things sufficient to show Your engagement of any third party to perform any part of any Clinical Trial (including statistical analysis) of any Other Eczema Drug Candidates or any Other Psoriasis Drug Candidates and all reasons You decided to engage such third parties, including without limitation any retention or engagement agreement for any such third party.

### **RESPONSE TO REQUEST FOR PRODUCTION NO. 41:**

Lilly objects to this Request as vague, ambiguous, overly broad, unduly burdensome, and not proportional to the needs of the case, including because it seeks "any party of any Clinical Trial," seeks "all reasons You decided to engage such third parties," and is unlimited as to timeframe. Lilly also objects

to this Request as not relevant to the claims or defenses of a party to the extent it seeks documents not relevant to whether the efforts, resources, and expertise Lilly devoted to REZPEG satisfied Lilly's commercially reasonable efforts obligations under the parties' License Agreement and to the extent it seeks documents concerning clinical trials and drug candidates that are not relevant to the issues in dispute in this case.

Subject to and without waiving its General and Specific Objections, Lilly will conduct a reasonable search for and produce non-privileged documents sufficient to show Lilly's engagement of any third party to perform statistical analysis of any phase 1 study for atopic dermatitis or psoriasis sponsored by Lilly from 2017 through 2023, including any retention or engagement agreement for such third party relating to such study.

#### **REQUEST FOR PRODUCTION NO. 42:**

Documents, Communications, and Things sufficient to show all statistical analysis plans for any Clinical Trial of any Other Eczema Drug Candidates or any Other Psoriasis Drug Candidates.

#### **RESPONSE TO REQUEST FOR PRODUCTION NO. 42:**

Lilly objects to this Request as overly broad, unduly burdensome, and not proportional to the needs of the case, including because it is unlimited as to timeframe. Lilly also objects to this Request as not relevant to the claims or defenses of a party to the extent it seeks documents not relevant to whether the efforts, resources, and expertise Lilly devoted to REZPEG satisfied Lilly's commercially reasonable efforts obligations under the parties' License Agreement and to the extent it seeks documents concerning clinical trials and drug candidates that are not relevant to the issues in dispute in this case.

Subject to and without waiving its General and Specific Objections, Lilly will conduct a reasonable search for and produce non-privileged documents sufficient to show the statistical analysis plans for any phase 1 study for atopic dermatitis or psoriasis sponsored by Lilly from 2017 through 2023.

#### **REQUEST FOR PRODUCTION NO. 43:**

All Documents, Communications, and Things concerning any effort by You to ensure accurate statistical analysis of any Clinical Trial of any Other Eczema Drug Candidates or any Other Psoriasis Drug Candidates, whether performed (or to be performed) by You or by a third party, including, for each such trial:

- all materials concerning any efforts to perform "appropriate database programming," conduct "accurate analyses," and perform "quality checks on those analyses"; and
- any "data," "guidance," and/or "oversight" You provided to any third party regarding the conduct of any such trial.

#### **RESPONSE TO REQUEST FOR PRODUCTION NO. 43:**

Lilly objects to this Request as vague, ambiguous, overly broad, unduly burdensome, and not proportional to the needs of the case, including because it seeks "[a]ll Documents, Communications, and Things concerning any effort," seeks "all materials concerning any efforts," and is unlimited as to timeframe. Lilly also objects to this Request as not relevant to the claims or defenses of a party to the extent it seeks documents not relevant to whether the efforts, resources, and expertise Lilly devoted to REZPEG satisfied Lilly's commercially reasonable efforts obligations under the parties' License Agreement and to the extent it seeks documents concerning clinical trials and drug candidates that are not relevant to the issues in dispute in this case. Lilly further objects to this Request because it seeks premature expert discovery.

Subject to and without waiving its General and Specific Objections, Lilly will conduct a reasonable search for and produce documents sufficient to show efforts Lilly took to ensure accurate statistical analysis of any phase 1 study for atopic dermatitis or psoriasis sponsored by Lilly from 2017 through 2023.

#### **REQUEST FOR PRODUCTION NO. 44:**

All Documents, Communications, and Things concerning any policies, procedures, or "practices" of You or a third party regarding any statistical analysis of any Clinical Trial of any Other Eczema Drug Candidates or any Other Psoriasis Drug Candidates.

#### **RESPONSE TO REQUEST FOR PRODUCTION NO. 44:**

Lilly objects to this Request as vague, ambiguous, overly broad, unduly burdensome, and not proportional to the needs of the case, including because it seeks "[a]ll Documents, Communications, and Things" and is unlimited as to timeframe. Lilly also objects to this Request as not relevant to the claims or defenses of a party to the extent it seeks documents not relevant to whether the efforts, resources, and expertise Lilly devoted to REZPEG satisfied Lilly's commercially reasonable efforts obligations under the parties' License Agreement and to the extent it seeks documents concerning clinical trials and drug

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candidates that are not relevant to the issues in dispute in this case. Lilly further objects to this Request as duplicative and cumulative of other Requests, including Request No. 39.

Subject to and without waiving its General and Specific Objections, Lilly will conduct a reasonable search for and produce non-privileged documents relating to the policies, procedures, or practices of Lilly or a third party regarding the statistical analysis of any phase 1 study for atopic dermatitis or psoriasis sponsored by Lilly from 2017 through 2023.

#### **REQUEST FOR PRODUCTION NO. 45:**

Documents, Communications, and Things sufficient to show all designs for any Clinical Trial of any Other Eczema Drug Candidates or any Other Psoriasis Drug Candidates, whether or not such trial was performed, whether injection site reaction information was solicited, and including but not limited to the selection and timing of interim analyses for any such trial.

#### **RESPONSE TO REQUEST FOR PRODUCTION NO. 45:**

Lilly objects to this Request as vague, ambiguous, overly broad, unduly burdensome, and not proportional to the needs of the case, including because it seeks "[a]ll designs for any Clinical Trial" and is unlimited as to timeframe. Lilly also objects to this Request as not relevant to the claims or defenses of a party to the extent it seeks documents not relevant to whether the efforts, resources, and expertise Lilly devoted to REZPEG satisfied Lilly's commercially reasonable efforts obligations under the parties' License Agreement and to the extent it seeks documents concerning clinical trials and drug candidates that are not relevant to the issues in dispute in this case.

Subject to and without waiving its General and Specific Objections, Lilly will conduct a reasonable search for and produce non-privileged documents sufficient to show the designs for any phase 1 study for atopic dermatitis or psoriasis and phase 2 study for atopic dermatitis sponsored by Lilly from 2017 through 2023.

#### **REQUEST FOR PRODUCTION NO. 46:**

Documents, Communications, and Things sufficient to show all primary and secondary endpoints considered and/or selected for any Clinical Trial of any Other Lupus Drug Candidates, whether or not such endpoint was ultimately selected for use in the study.

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#### **RESPONSE TO REQUEST FOR PRODUCTION NO. 46:**

Lilly objects to this Request as vague, ambiguous, overly broad, unduly burdensome, and not proportional to the needs of the case, including because it seeks "all primary and secondary endpoints considered" and is unlimited as to timeframe. Lilly also objects to this Request as not relevant to the claims or defenses of a party to the extent it seeks documents not relevant to whether the efforts, resources, and expertise Lilly devoted to REZPEG satisfied Lilly's commercially reasonable efforts obligations under the parties' License Agreement and to the extent it seeks documents concerning clinical trials and drug candidates that are not relevant to the issues in dispute in this case.

Subject to and without waiving its General and Specific Objections, Lilly will conduct a reasonable search for and produce non-privileged documents sufficient to show the primary and secondary endpoints selected for any phase 2 study for SLE that Lilly sponsored from 2017 through 2023.

#### **REQUEST FOR PRODUCTION NO. 47:**

Documents, Communications, and Things sufficient to show all reasons and/or basis for either selecting or rejecting any endpoint referenced in Request for Production No. 46.

#### **RESPONSE TO REQUEST FOR PRODUCTION NO. 47:**

Lilly objects to this Request as vague, ambiguous, overly broad, unduly burdensome, and not proportional to the needs of the case, including to the extent it seeks "all reasons" and because it is unlimited as to timeframe. Lilly also objects to this Request as not relevant to the claims or defenses of a party to the extent it seeks documents not relevant to whether the efforts, resources, and expertise Lilly devoted to REZPEG satisfied Lilly's commercially reasonable efforts obligations under the parties' License Agreement and to the extent it seeks documents concerning clinical trials and drug candidates that are not relevant to the issues in dispute in this case.

Lilly is willing to meet and confer to narrow the scope of this Request to materials, if any, that are relevant to the allegations in the Complaint and issues in dispute in this action and proportional to the needs of the case.

#### **REQUEST FOR PRODUCTION NO. 48:**

Documents, Communications, and Things sufficient to show the planned and actual enrollment for any Clinical Trial of any Other Lupus Drug Candidates.

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#### **RESPONSE TO REQUEST FOR PRODUCTION NO. 48:**

Lilly objects to this Request as vague, ambiguous, overly broad, unduly burdensome, and not proportional to the needs of the case, including because it is unlimited as to timeframe. Lilly also objects to this Request as not relevant to the claims or defenses of a party to the extent it seeks documents not relevant to whether the efforts, resources, and expertise Lilly devoted to REZPEG satisfied Lilly's commercially reasonable efforts obligations under the parties' License Agreement and to the extent it seeks documents concerning clinical trials and drug candidates that are not relevant to the issues in dispute in this case.

Subject to and without waiving its General and Specific Objections, Lilly will conduct a reasonable search for and produce non-privileged documents sufficient to show the planned and actual enrollment for any phase 2 study for SLE that Lilly sponsored from 2017 through 2023.

#### **REQUEST FOR PRODUCTION NO. 49:**

All Documents, Communications, and Things concerning the safety of all Other Eczema Drug Candidates, all Other Psoriasis Drug Candidates, and all Other Lupus Drug Candidates, including all known adverse events (of any severity) associated with each.

#### **RESPONSE TO REQUEST FOR PRODUCTION NO. 49:**

Lilly objects to this Request as vague, ambiguous, overly broad, unduly burdensome, and not proportional to the needs of the case, including because it seeks "[a]ll Documents, Communications, and Things" and is unlimited as to timeframe. Lilly also objects to this Request as not relevant to the claims or defenses of a party to the extent it seeks documents not relevant to whether the efforts, resources, and expertise Lilly devoted to REZPEG satisfied Lilly's commercially reasonable efforts obligations under the parties' License Agreement and to the extent it seeks documents concerning drug candidates that are not relevant to the issues in dispute in this case. Lilly further objects to this Request as duplicative and cumulative of other Requests, including Request No. 13.

Subject to and without waiving its General and Specific Objections, Lilly will conduct a reasonable search for and produce non-privileged documents reflecting Lilly's consideration of REZPEG's safety in relation to other drugs for which Lilly has sponsored clinical trials for atopic dermatitis, psoriasis, and

lupus. Lilly will not search for or produce documents solely related to the safety of other such drugs to the extent unrelated to REZPEG, the allegations in the Complaint, or the issues in dispute in this action.

#### **REQUEST FOR PRODUCTION NO. 50:**

All Documents, Communications, and Things concerning the efficacy of all Other Eczema Drugs, all Other Psoriasis Drugs, and all Other Lupus Drugs, including the efficacy shown in any human study or Clinical Trial of each.

#### **RESPONSE TO REQUEST FOR PRODUCTION NO. 50:**

Lilly objects to this Request as vague, ambiguous, overly broad, unduly burdensome, and not proportional to the needs of the case, including because it seeks "[a]ll Documents, Communications, and Things" and is unlimited as to timeframe. Lilly also objects to this Request as not relevant to the claims or defenses of a party to the extent it seeks documents not relevant to whether the efforts, resources, and expertise Lilly devoted to REZPEG satisfied Lilly's commercially reasonable efforts obligations under the parties' License Agreement and to the extent it seeks documents concerning drug candidates that are not relevant to the issues in dispute in this case. Lilly further objects to this Request as duplicative and cumulative of other Requests, including Request No. 12.

Subject to and without waiving its General and Specific Objections, Lilly will conduct a reasonable search for and produce non-privileged documents reflecting Lilly's consideration of REZPEG's efficacy in relation to other drugs for which Lilly has sponsored clinical trials for atopic dermatitis, psoriasis, and lupus. Lilly will not search for or produce documents solely related to the efficacy of other such drugs to the extent unrelated to REZPEG, the allegations in the Complaint, or the issues in dispute in this action.

#### **REQUEST FOR PRODUCTION NO. 51:**

All Documents, Communications, and Things concerning the severity, frequency, and prevalence of injection site reactions for all Other Eczema Drug Candidates, all Other Psoriasis Drug Candidates, and all Other Lupus Drug Candidates.

#### **RESPONSE TO REQUEST FOR PRODUCTION NO. 51:**

Lilly objects to this Request as vague, ambiguous, overly broad, unduly burdensome, and not proportional to the needs of the case, including because it seeks "[a]ll Documents, Communications, and Things" and is unlimited as to timeframe. Lilly also objects to this Request as not relevant to the claims

or defenses of a party to the extent it seeks documents not relevant to whether the efforts, resources, and expertise Lilly devoted to REZPEG satisfied Lilly's commercially reasonable efforts obligations under the parties' License Agreement and to the extent it seeks documents concerning drug candidates that are not relevant to the issues in dispute in this case. Lilly further objects to this Request as duplicative and cumulative of other Requests, including Request No. 16, 17, and 52.

Subject to and without waiving its General and Specific Objections, Lilly will conduct a reasonable search for and produce responsive, non-privileged documents relating to the severity, frequency, and prevalence of injection site reactions associated with other injectable drugs for atopic dermatitis, psoriasis, or lupus to the extent related to Lilly's development of REZPEG.

#### **REQUEST FOR PRODUCTION NO. 52:**

All Documents, Communications, and Things concerning Your understanding of the commercial acceptability of injection site reactions associated with all Other Eczema Drug Candidates, all Other Psoriasis Drug Candidates, and all Other Lupus Drug Candidates, including, without limitation, any research You conducted regarding the commercial acceptability of injection site reactions.

#### **RESPONSE TO REQUEST FOR PRODUCTION NO. 52:**

Lilly objects to this Request as overly broad, unduly burdensome, and not proportional to the needs of the case, including because it seeks "[a]ll Documents, Communications, and Things" and is unlimited as to timeframe. Lilly also objects to this Request as vague and ambiguous, including because it seeks Lilly's "understandings of the commercial acceptability of injection site reactions." Lilly also objects to this Request as not relevant to the claims or defenses of a party to the extent it seeks documents not relevant to whether the efforts, resources, and expertise Lilly devoted to REZPEG satisfied Lilly's commercially reasonable efforts obligations under the parties' License Agreement and to the extent it seeks documents concerning drug candidates that are not relevant to the issues in dispute in this case. Lilly further objects to this Request as duplicative and cumulative of other Requests, including Request Nos. 16, 17, and 51.

Subject to and without waiving its General and Specific Objections, Lilly will conduct a reasonable search for and produce responsive, non-privileged documents relating to Lilly's understanding of the

 commercial acceptability of injection site reactions associated with other injectable drugs for atopic dermatitis, psoriasis, or lupus to the extent related to Lilly's development of REZPEG.

#### **REQUEST FOR PRODUCTION NO. 53:**

Documents, Communications, and Things sufficient to show the costs of performing any Clinical Trial for REZPEG, all Other Eczema Drug Candidates, all Other Psoriasis Drug Candidates, and all Other Lupus Drug Candidates.

#### **RESPONSE TO REQUEST FOR PRODUCTION NO. 53:**

Lilly objects to this Request as vague, ambiguous, overly broad, unduly burdensome, and not proportional to the needs of the case, including because it is unlimited as to timeframe. Lilly also objects to this Request as not relevant to the claims or defenses of a party to the extent it seeks documents not relevant to whether the efforts, resources, and expertise Lilly devoted to REZPEG satisfied Lilly's commercially reasonable efforts obligations under the parties' License Agreement and to the extent it seeks documents concerning clinical trials and drug candidates that are not relevant to the issues in dispute in this case.

Lilly is willing to meet and confer to narrow the scope of this Request to materials, if any, that are relevant to the allegations in the Complaint and issues in dispute in this action and proportional to the needs of the case.

#### **REQUEST FOR PRODUCTION NO. 54:**

Documents, Communications, and Things sufficient to show all "go" and/or "no-go" decisions made at any time for REZPEG, all Other Eczema Drug Candidates, all Other Psoriasis Drug Candidates, and all Other Lupus Drug Candidates, including items sufficient to show all factors and reasons underlying such decisions.

#### **RESPONSE TO REQUEST FOR PRODUCTION NO. 54:**

Lilly objects to this Request as overly broad, unduly burdensome, and not proportional to the needs of the case, including because it seeks "[a]ll Documents, Communications, and Things" and is unlimited as to timeframe. Lilly also objects to this Request as vague and ambiguous, including because it seeks materials concerning "all 'go' and or 'no-go' decisions," without defining the same. Lilly also objects to this Request as not relevant to the claims or defenses of a party to the extent it seeks documents not

relevant to whether the efforts, resources, and expertise Lilly devoted to REZPEG satisfied Lilly's commercially reasonable efforts obligations under the parties' License Agreement and to the extent it seeks documents concerning clinical trials and drug candidates that are not relevant to the issues in dispute in this case.

Lilly is willing to meet and confer to narrow the scope of this Request to materials, if any, that are relevant to the allegations in the Complaint and issues in dispute in this action and proportional to the needs of the case.

#### **REQUEST FOR PRODUCTION NO. 55:**

Documents, Communications, and Things sufficient to show the timing and scope of actual and/or projected Clinical Trial(s) for all Other Eczema Drug Candidates, all Other Psoriasis Drug Candidates, and all Other Lupus Drug Candidates, including items sufficient to show:

- The number of Clinical Trials for each such drug or drug candidate (actual or projected), including but not limited to the treatment of atopic dermatitis, psoriasis, and/or systemic lupus erythematosus, and including early-phase studies without a specific indication;
- The indication(s) under investigation in each Clinical Trial, if applicable;
- The enrollment of each Clinical Trial (actual and/or projected);
- The start and end dates for each Clinical Trial (actual and/or projected).

### **RESPONSE TO REQUEST FOR PRODUCTION NO. 55:**

Lilly objects to this Request as vague, ambiguous, overly broad, unduly burdensome, and not proportional to the needs of the case, including because it is unlimited as to timeframe. Lilly also objects to this Request as not relevant to the claims or defenses of a party to the extent it seeks documents not relevant to whether the efforts, resources, and expertise Lilly devoted to REZPEG satisfied Lilly's commercially reasonable efforts obligations under the parties' License Agreement and to the extent it seeks documents concerning clinical trials and drug candidates that are not relevant to the issues in dispute in this case. Lilly further objects to this Request as duplicative and cumulative of other Requests, including Request Nos. 45 and 48.

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Lilly is willing to meet and confer to narrow the scope of this Request to materials, if any, that are relevant to the allegations in the Complaint and issues in dispute in this action and proportional to the needs of the case.

#### **REQUEST FOR PRODUCTION NO. 56:**

Documents, Communications, and Things sufficient to show the timing and scope of actual and/or projected preclinical (animal) studies for all Other Eczema Drug Candidates, all Other Psoriasis Drug Candidates, and all Other Lupus Drug Candidates, including items sufficient to show:

- The number of preclinical studies for each such drug or drug candidate;
- The type of each such preclinical study;
- The type and number of animals to be used in any preclinical study (actual or projected);
- The start and end dates for each preclinical study (actual and/or projected).

#### **RESPONSE TO REQUEST FOR PRODUCTION NO. 56:**

Lilly objects to this Request because it seeks materials not relevant to the claims or defenses of a party. Lilly also objects to this Request as vague, ambiguous, overly broad, unduly burdensome, and not proportional to the needs of the case, including because it is unlimited as to timeframe.

Lilly will not produce documents responsive to this Request.

#### **REQUEST FOR PRODUCTION NO. 57:**

Documents, Communications, and Things sufficient to show the probability of technical success and the probability of regulatory success for all Other Eczema Drug Candidates, all Other Psoriasis Drug Candidates, and all Other Lupus Drug Candidates at the time You designed any Clinical Trial for each such drug or drug candidate.

#### **RESPONSE TO REQUEST FOR PRODUCTION NO. 57:**

Lilly objects to this Request as vague, ambiguous, overly broad, unduly burdensome, and not proportional to the needs of the case, including because it seeks materials showing "the probability of technical success and the probability of regulatory success" without specifying from whose perspective such probability should be determined and because there is not necessarily one discrete "time [Lilly] designed any Clinical Trial for each such drug or drug candidate." Lilly also objects to this Request as not relevant to the claims or defenses of a party to the extent it seeks documents not relevant to whether

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the efforts, resources, and expertise Lilly devoted to REZPEG satisfied Lilly's commercially reasonable efforts obligations under the parties' License Agreement and to the extent it seeks documents concerning clinical trials and drug candidates that are not relevant to the issues in dispute in this case.

Lilly is willing to meet and confer to narrow the scope of this Request to materials, if any, that are relevant to the allegations in the Complaint and issues in dispute in this action and proportional to the needs of the case.